

LABEL, IN PART: (Box) "Uni-Swabs 80 Individual Swabs in Cellophane Packets Sterile when Packed."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, namely, "Sterile when Packed."

Misbranding, Section 502 (a), the label statement "Sterile when Packed" was false and misleading as applied to an article which was not sterile when packed but which was contaminated with living micro-organisms.

DISPOSITION: July 11, 1952. Default decree of condemnation and destruction.

3791. Adulteration and misbranding of adhesive bandages. U. S. v. 40 Cartons
* * *. (F. D. C. No. 33298. Sample No. 37808-L.)

LIBEL FILED: June 17, 1952, District of New Jersey.

ALLEGED SHIPMENT: On or about April 21, 1952, by American White Cross Labs., Inc., from New Rochelle, N. Y.

PRODUCT: 40 cartons, each containing 12 boxes, of *adhesive bandages* at Newark, N. J.

LABEL, IN PART: (Carton) "One Dozen American White Cross Waterproof Adhesive Bandages Ten's Mercurochrome Pad"; (box) "American White Cross Sterile Waterproof 10 Adhesive Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard in that it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile" was false and misleading.

DISPOSITION: August 8, 1952. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3792. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. 43,000 Tablets * * *. (F. D. C. No. 33103. Sample No. 12723-L.)

LIBEL FILED: April 28, 1952, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 11, 1952, by the Robin Pharmacal Corp., from Brooklyn, N. Y.

PRODUCT: 43,000 *dextro-amphetamine sulfate tablets* at Cleveland, Ohio. Analysis showed that the product was racemic amphetamine sulfate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Dextro-Amphetamine Sulfate" was false and misleading as applied to the article, which was racemic amphetamine sulfate.

DISPOSITION: May 23, 1952. Default decree of condemnation and destruction.

3793. Misbranding of Nutrient tablets, Inorganic Nutrient tablets, soyabean oil, and soya lecithin. U. S. v. 1 Bottle, etc. (F. D. C. No. 31398. Sample Nos. 23455-L, 23456-L, 23458-L, 23459-L.)

LIBEL FILED: August 9, 1951, Northern District of New York.

*See also Nos. 3783-3786, 3789-3791.

ALLEGED SHIPMENT: On or about May 19, June 11 and 25, and July 3, 1951, by Inorganic Bioelements, Inc., from Cleveland, Ohio.

PRODUCT: 2 60-tablet bottles of *Nutrient tablets*, 1 500-tablet bottle and 5 60-tablet bottles of *Inorganic Nutrient tablets*, 10 1-pint bottles of *soyabean oil*, and 5 8-ounce bottles of *soya lecithin* at Binghamton, N. Y.

LABEL, IN PART: (Bottle) "Inorganic Nutrient Tablets * * * Each tablet contains 170 mg. Manganese Sulfate, 1 mg. Copper Sulfate, 3 mg. Cobalt Sulfate, 1 mg. Zinc Sulfate, 10 mg. Iron Sulfate in combination with Lecithin * * * Directions Adults: 2 tablets daily * * * Children (10-16 years): one tablet daily," "Nutrient Tablets (Multiple Trace Elements containing Manganese in the organic form of an Amino Acid Salt.) Each tablet contains: 155 mg. Manganese Glutamate, 1 mg. Copper Sulfate, 3 mg. Cobalt Sulfate, 1 mg. Zinc Sulfate, 10 mg. Iron Sulfate in combination with Lecithin. * * * Directions Adults: 2 tablets daily * * * Children (10-16 years): one tablet daily," "One Pint Soyabean Oil," and "Soya Lecithin, Refined Edible, Oil Free * * * 8 Ounces Net."

NATURE OF CHARGE: *Nutrient tablets* and *Inorganic Nutrient tablets*. Misbranding, Section 502 (a), certain statements on the bottle labels and in booklets and leaflets accompanying the articles, namely, "Notes on Inorganic Bioelements," "Retail Price List," "Brucellosis and Mastitis," "Inorganic Bioelements in Nutrition," "Health vs. Disease," and "Bangs Disease and Undulant Fever are due to Nutritional Deficiencies," were false and misleading. The statements represented and suggested that the articles were effective to correct deficiencies of the relative essential elements and their consequences; that manganese, cobalt, and zinc play an essential role in nutrition and body functions, and that an insufficient quantity of such elements in the food supply will lead to so-called deficiency diseases and invite the invasion of disease organisms, whereas their adequate presence would prevent the entrance of pathogens into the blood stream; that due to their cobalt content the articles would help to mature red blood cells, depress certain intestinal pathogens, activate internal micro-organisms that split carbohydrates and proteins for better food assimilation, perform enzyme and enzyme substrate functions in the form of a metal proteid, and were of fundamental importance; that because of their cobalt sulfate content, the articles would relieve deficiencies when administered orally; that due to their manganese content, the articles would act as a catalyst to bind calcium and phosphorus into bones, help to perform chemical reactions and to reverse them, and activate iron and conduct it to the proper place in the hemoglobin molecule of the red blood cells; that manganese is as important as iron for the generation and regeneration of hemoglobin because it is in all probability the coenzyme of a proteid in hemoglobin synthesis; that manganese is related to the formation of the vitamins A, C, and E; that the articles were a positive cure for diabetes; that supplements of inorganic nutriment have certain advantages when they contain available sulfate ions; that the effect of sulfates in the articles was buffered by the lecithin present; that the articles would balance the contents of essential inorganic bio-elements in modern diets; that the articles were an adequate and effective treatment for Brucella infection (undulant fever), and such symptoms as alternating fevers and chills, headaches, backaches, pains behind the knees, loss of weight, loss of strength, olive-colored skin, intolerance to light, fear of imminent danger, gastric ulcers, arthritis, rheumatism and

influenza, mastitis, caked breast, diabetes, Buerger's disease (thromboangiitis obliterans), arthritic conditions, sciatica, lumbago, bone fractures (nonhealing bones), Paget's disease, sterility before and during treatment with hormones, and all cases of malnutrition, nervousness, stomach trouble, and incurable eczema; that the articles were effective as a nutritional fortification before and after surgical operations and during period of pregnancy and nursing; and that the administration of sulfa drugs, antibiotics, and vitamins would be more effective when preceded and followed by the articles. These statements were contrary to fact.

Soyabean oil. Misbranding, Section 502 (a), certain statements in the leaflet which accompanied the article and which was entitled "Retail Price List" were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for poor skin conditions, underweight, arthritis, and scaly skin. The article was not an adequate and effective treatment for these conditions.

Soya lecithin. Misbranding, Section 502 (a), certain statements in the circular entitled "Oil Free Soyabean Lecithin Edible" and leaflet entitled "Retail Price List," which accompanied the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for hardening of the arteries, high and low blood pressure, hypertension, calcination of the spine or other parts of the skeleton, psoriasis, and pulmonary troubles; that it was effective in the prevention of fatty livers; and that it would check tendencies toward arteriosclerosis. These statements were contrary to fact.

The articles were misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: January 14, 1952. Default decree of condemnation and destruction.

3794. Misbranding of In-Flam-Go. U. S. v. 60 Bottles, etc. (F. D. C. No. 33236. Sample No. 31615-L.)

LABEL FILED: May 6, 1952, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about July 25, 1951, by the In-Flam-Go Products Co., from Detroit, Mich.

PRODUCT: 60 1-pint bottles and 95 ½-pint bottles of *In-Flam-Go*, at St. Louis, Mo., together with a number of leaflets headed "It Will Surprise You" and "A Truly Remarkable Product" and a display easel headed "In-Flam-Go," which accompanied the product. Analysis showed that the product was an oily solution containing a small amount of iodine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label, in the accompanying leaflets, and on the display easel were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for inflammation, goiter, varicose veins, sprains, arthritis, neuritis, styes, burns and scalds, underactive and overactive thyroid glands, neuralgia, backache, sore muscles, bruises, impetigo, varicose ulcers, gangrene, hardening of the arteries, tonsillitis, sore throat, ringworm, eczema, sinus conditions, swelling of the glands, and high blood pressure. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: June 27, 1952. Default decree of condemnation and destruction.